

A Physician Assistant-led randomized controlled trial (RCT) to improve outcomes following Breast Cancer Surgery using a Jackson Pratt (JP) drain milking device

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Introduction

- Breast cancer patients undergoing mastectomy or axillary lymph node dissection (ALND) are routinely discharged home with a Jackson Pratt (JP) drain left in to reduce the risk of developing a seroma.
- Common drain-related complications after surgery include leaking around drain, clogged drain tubing, pain, bleeding and infection.
- It is our clinical impression that the management of these drains at home is difficult for patients, requiring multiple community nursing visits and often leads to unplanned healthcare visits to family doctor or the surgeon's office.

Objective

A pilot RCT to track the patient experience with JP drain care at home and to evaluate the effectiveness of "Tube-Evac", a JP drain milking device, in reducing drain-related complications and unscheduled healthcare visits following Breast Surgery

Method

- All elective breast surgery patients at a tertiary care, academic hospital, meeting the inclusion criteria were randomly assigned to the "Tube-Evac" group (intervention arm) or standard care group (control arm).
- Inclusion criteria: (i) patients >18 years, (ii) undergoing mastectomy and/or ALND (iii) understood English
- For this pilot study, 100 consecutive patients were selected.

Recruitment and Follow up

- Patients in the control group received standard drain care and post-operative discharge instructions.
- In addition to standard care, patients in the intervention group were provided a "Tube-Evac", JP drain milking device. Physician Assistants (PAs) demonstrated to patients how to use the device and provided an education handout.
- All patients were asked to complete a log sheet to track community nursing visits and drain-related complications. The PAs called all patients on post-discharge day 7 to complete a telephone survey and to collect outcome data.

Figure 1: Study outcomes

Primary	Secondary
<ul style="list-style-type: none"> drain related complications number of unplanned healthcare visits number of community nursing visits Satisfaction with Tube-Evac 	<ul style="list-style-type: none"> number of post-operative days with a drain confidence managing JP drain(s)

Figure 2. Post-mastectomy JP drain and manual drain milking

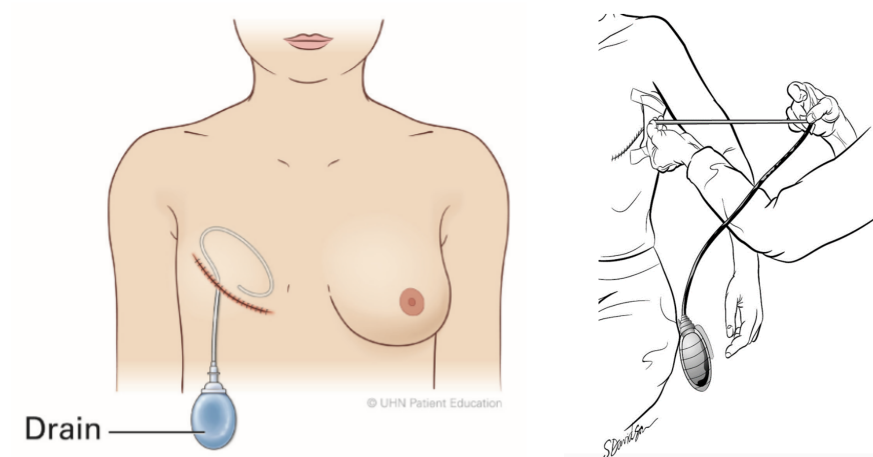
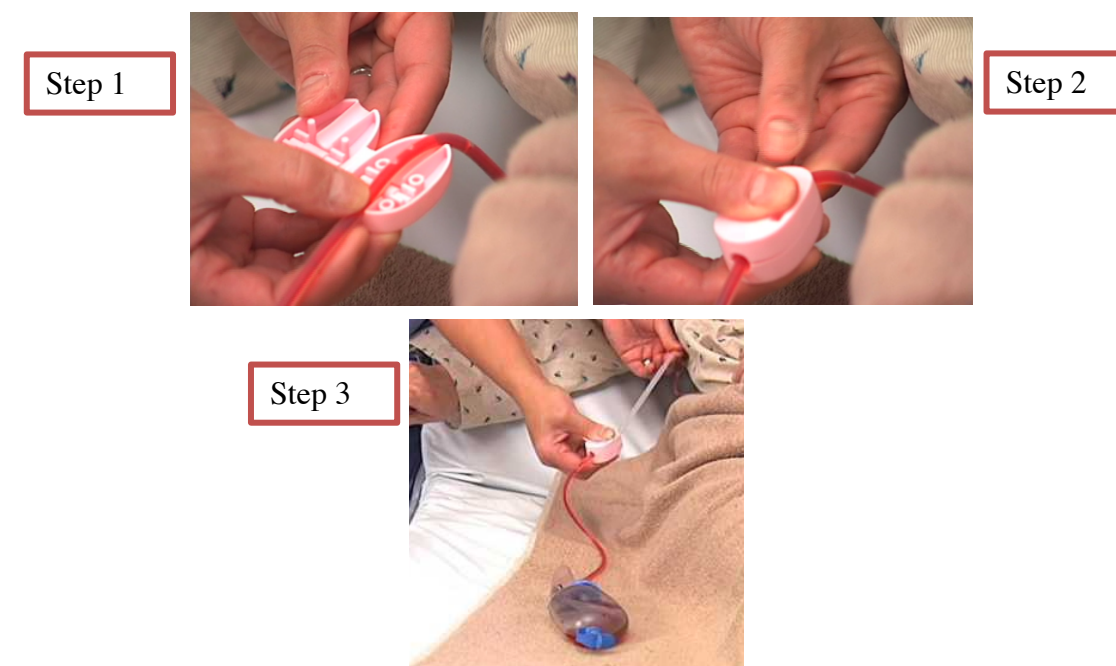


Figure 3. JP drain milking using the Tube-Evac device



Results

The interim results are presented for 58 patients (29 intervention, 29 control).

Table 1: Demographics

Demographics	Intervention (n=29)	Control (n=29)	P-value
Age, years (median) [SD]	59 [±16.27]	58 [±13.29]	1.0
Procedure, n (%)			1.0
Unilateral Mastectomy	15 (52%)	13 (45%)	
Bilateral Mastectomy	4 (14%)	6 (21%)	
ALNDx	3 (10%)	4 (13%)	
Combined M+A	7 (24%)	6 (21%)	
# of Drains per Patient, n (%)			0.78
One	18 (62%)	19 (65%)	
Multiple	11 (38%)	10 (35%)	
Follow up response rate, n (%)	27 (93%)	29 (100%)	

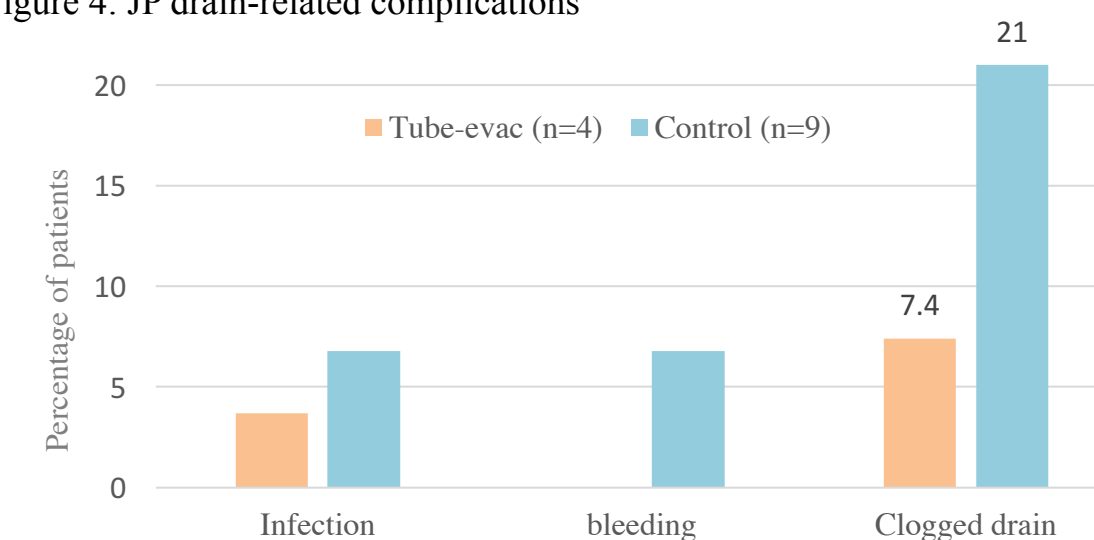
Patient demographics were the same in both groups for all baseline characteristics.

Table 2. Primary outcomes

Primary outcome	Intervention (n=27)	Control (n=29)	P-value
Patients with Drain Complication(s), n (%) i.e. Infection, Bleeding, leaking	4 (14%)	10 (34%)	<i>p=0.08</i>
Unscheduled MD visits, n	2	5	<i>p=0.26</i>
Community Nursing Visits, mean [SD]	3.10 [±1.05]	4.14 [±1.73]	<i>p=0.007</i>

- In the intervention arm, there is a trend towards decreased rate of drain-related complications (14% vs 34%) and fewer unplanned healthcare visits (2 vs 5).
- The average number of community nursing visits were significantly lower in the intervention arm (3.10 vs 4.14).

Figure 4: JP drain-related complications



More patients complained of clogged drain tubing in the control group as compared to the intervention arm [21% (n=6) vs. 7.4% (n=2)].

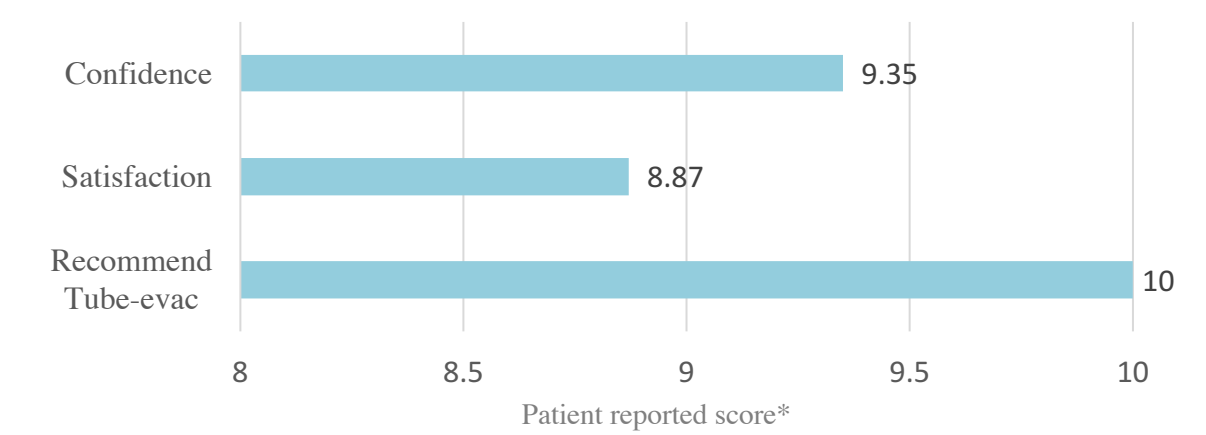
Table 3: Secondary outcomes

Secondary outcome	Intervention (n=27)	Control (n=29)	P-value
Days with drain(s), mean [SD]	9.74 [±3.81]	12.68 [±6.44]	<i>p=0.04</i>
Patients with drains removed within 14 day, n (%)	23 (85%)	18 (62%)	<i>p= 0.05</i>
Comfortable managing JP drain, mean (median) SD*	8.28 (9) [±2.17]	7.0 (8) [±2.91]	<i>p=0.067</i>

* Scale of 1-10 (1=none of the time, 10=all the time)

- Patients in the intervention group had the drain in for a significantly shorter period of time compared to the control group (9.74 vs 12.68 days). More patients in the intervention group had their drains removed within 14 days (85% vs 62%).
- Patients in the intervention arm reported higher scores for feeling comfortable managing their drain at home than the control group (8.28 vs 7.0).

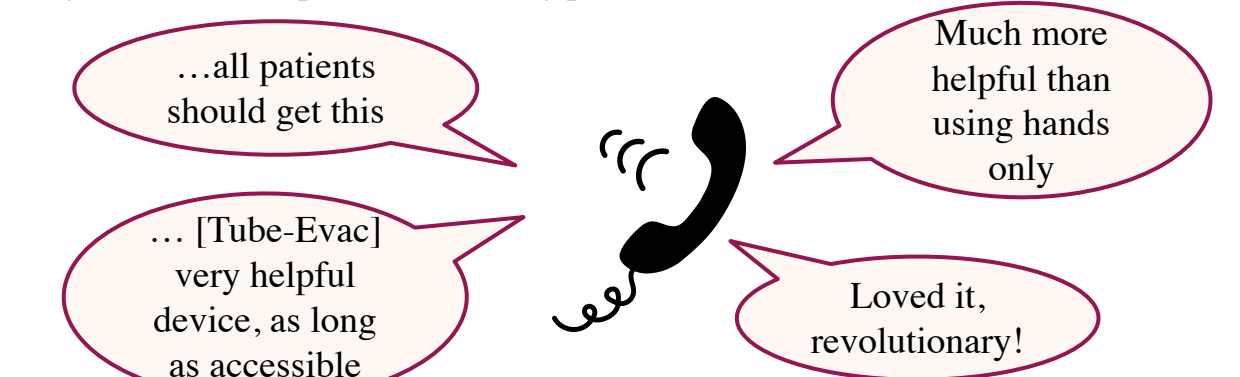
Figure 5: patient experience using the Tube-Evac in the intervention group (n=27)



* Scale of 1-10 (1=none of the time, 10=all the time)

- In the intervention group, the mean score on all patient reported outcomes indicated high patient confidence and satisfaction using the Tube-Evac device.
- The Tube-Evac device was recommended by 100% of the patients (n=27)

Figure 6: Patient quotes illustrating patient satisfaction with Tube-Evac



Discussion

- The Tube-Evac showed a decrease in drain-related complication, fewer unplanned visits to family doctor's office and a decreased in community nursing visit requirements compared to the control group.
- Patients using the Tube-Evac drain milking device had their drains removed sooner and felt more comfortable managing their drains at home compared to the control group.
- The Tube-Evac device is viewed positively by patients due to high rates of satisfaction. It was recommended by all patients in the intervention arm.

Conclusion

- Breast surgery patients experience difficulties managing JP drains postoperatively resulting in drain-related complications prompting visits to family doctor or the surgeon's office.
- Preliminary results suggest that the "Tube-Evac" is a successful strategy to decrease drain-related complications and unplanned postoperative healthcare visits, while improving patient confidence with managing their surgical drain(s) at home.
- Tube-Evac is likely a feasible means to having JP drains removed sooner in breast surgery patients.
- Upon completion of the pilot study, our next step is to directly track patient anxiety associated with breast JP drain care in a larger sample size.